

Docket No.:

UNITED STATES PATENT & TRADEMARK OFFICE

| | |
|-------------|---------------------------|
| Examiner: | Art Unit: |
| Applicant: | CHOI, Young Kweon et al. |
| Serial No.: | 10/729,648 |
| Filed | December 5, 2003 |
| For: | PATCH FOR TOOTH WHITENING |

DECLARATION OF TRANSLATOR

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

I, Won-Hee Lee, declare and state:

- 1) My address is: 8th Fl. Sung-ji Heights II, 642-16 Yoksam-dong, Kangnam-ku, Seoul, 135-080, Republic of Korea;
- 2) I speak and write Korean;
- 3) I have prepared the attached translation into English of Korean Patent Application No. 2003/0027455;
- 4) I hereby certify that the attached English translation is a true and accurate translation of the aforementioned document;
- 5) The undersigned declares further that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

June 29, 2007
Date

By:



Won-Hee Lee (print name)

【Abstract】

The present invention relates to a patch for tooth whitening consisting peroxides as a tooth-whitening agent within erodible polymer film, wherein the patch, when adhered to the teeth, releases a peroxide tooth-whitening agent while being hydrated during a prescribed period, and thereafter, eroded by water in the mouth until extinguished, thereby not requiring an additional detaching work from the teeth. Therefore, the patch is convenient in use and able to greatly reduce an aversion to a foreign substance as well as has an excellent whitening effect.

【Model Figure】

Figure 1

【References】

Tooth-whitening agent, peroxides, an erodible polymer film, a patch for tooth whitening

【Specification】

【Title of the invention】

The tooth whitening patch using erodible polymer film

【Brief description of the drawings】

Fig. 1 is a view of a tooth-whitening patch for the upper teeth according to the present invention,

Fig. 2 is a view of a tooth-whitening patch for the lower teeth according to the present invention,

Fig. 3 is a cross-sectional view of a tooth-whitening patch according to the present invention;

1: an erodible drug layer,

Fig. 4 is a cross-sectional view of a tooth-whitening patch in the form of a double-layer structure;

1: an erosion rate-controlling layer;

2: an erodible drug layer,

Fig. 5 is a cross-sectional view of a tooth-whitening patch in the form of a triple-layer structure;

1: a first erosion rate-controlling layer;

2: a second erosion rate-controlling layer;

3: an erodible drug layer,

Fig. 6 is a cross-sectional view of a tooth-whitening patch in the form of a quadruple-layer structure;

1: a first erosion rate-controlling layer;

2: a second erosion rate-controlling layer;

3: a third erosion rate-controlling layer;

4: an erodible drug layer.

【Detailed description of the invention】

【Purport of the invention】

【Background Arts】

The present invention relates to a tooth-whitening patch containing peroxides as a tooth-whitening agent within an erodible polymer film.

The erodible polymer film is a kind of drug in the form of the film which is solved or swollen by water in the mouth and then gradually extinguished. According to the present invention, the tooth-whitening patch consists of polymers with hydrophilic property such as water-soluble or water-swollen polymers and a combination thereof, wherein the combination includes all of a physical mixture made simply by blending polymers and a complex made by polymer interaction such as a hydrogen bond, an ionic bond and the like.

A tooth is composed of an inner dentine layer and an outer hard enamel layer functioning to protect the inner parts of the teeth from infection and decay. The enamel layer is composed of about 96% inorganic materials and about 4% organic materials and water. The inorganic crystals themselves are colorless and transparent. However, spaces exist between the inorganic mineral crystals, which contain organic materials including proteins. Staining substances often

penetrate the spaces. The staining substances originated from what we eat and drink can penetrate into the teeth for several years and after all lead to a yellow staining of the teeth. Such a problem has been made gradually for several years and leads to a serious yellow staining of the enamel layer of the teeth. Even though the yellow-stained or decolored teeth are still healthy and do not cause any health problem, they are much in need of a material or product to whiten the yellow-stained teeth for the sake of beauty. Recently the stronger the tendency to place a high value on physical appearance becomes, the more interest in the tooth-whitening increases.

Most of the present whitening techniques has originated from a use of hydrogen peroxide to whiten the teeth at the close of 18th century. In the 19th century, since a practical use of light and hydrogen peroxides was reported for the first time, hydrogen peroxide solution together with other heats and a light source(including a laser) has been used as a tooth-whitening agents for the decades. However, there is a fault that most of these "in-office" tooth-whitening techniques require a lot of time, visiting a dentist ever so often and rubber dam as well as a heavy cost.

Accordingly, a first"at-home" tooth-whitening apparatus was developed in the end of 1980's, which uses a night guard generally containing a hydrogen peroxide or carbamide peroxide gel. Currently, such a method is the most popular in tooth whitening. However, since the peroxide gel is used in a high concentration, such a method is problematic with respect to convenience in use and safety, such as the case that gum is irritated by the excessive peroxide gel and a tray.

To solve these problems, various tooth-whitening products have been developed by employing peroxides of low concentrations without use of the mouth tray.

U.S. Pat. Nos. 5,879,691, 5,891,453 and 5,989,569 and International Pat. Publication No. WO98/55044 disclose a film formulation prepared by coating a transparent and pliable polyethylene film with a carbamide gel containing a peroxide instead of a mouth

tray, thereby improving the convenience of use and not making any trouble in our daily lives since it is transparent and thin when adhered to the tooth. However, it is some problems that when the pliable polyethylene film is coated with the fluent gel, included high concentration of hydrogen peroxide gel is apt to stick to the teeth or hands, tongue, gums, etc and moreover the polyethylene film must be removed after a prescribed time.

U.S. Pat. No. 6,083,421 disclose a film formulation prepared by melting and mixing an organic solvent such as ethylacetate with a polymer such as polyvinyl, butyral, shellac and a carbamide peroxide. This film has a problem that it lacks of adhering power to the teeth surfaces and must be removed after a prescribed time.

U.S. Pat. Nos. 6,419,906, 6,503,486 and 6,514,483 disclose film formulations prepared by mixing polyethylene oxide with peroxides. However, use of only polyethylene oxide does not give sufficient adhering ability to the teeth surfaces to the film. In addition, the film is rapidly solubilized in the mouth and thus does not guarantee a sufficient time for release of the peroxide in a desired amount.

Korean Pat. Laid-open Publication Nos. 10-2002-96264, 10-2002-97297, 10-2002-97298, 10-2003-299, 10-2003-1297 and 10-2003-3973 disclose dry-type patches for tooth whitening, which are prepared by mixing a hydrophilic polymer such as polyvinylpyrrolidone with peroxides, a peroxide-stabilizing agent and the like. In order to prepare such dry-type patches, a tooth-adhering layer contains a hydrophilic polymer(glass polymer), which cannot adhere to the teeth surfaces or has a weak adhesive strength under a dry condition, and, when the whitening agent is applied to a desired area of the teeth and then hydrated by a small amount of water thereon, come to have an ability to adhere to the teeth surfaces or a strong adhesive strength and to release a desired substance.

They are characterized in that a whitening agent is not released during the custody or when we touched them to adhere them to the teeth, but when they are hydrated by water from the surfaces of the teeth, the adhesive strength and the release of whitening agent occur.

However, these kinds of patches are inconvenient in use since they must be removed after being applied to the teeth during a prescribed time since a water-insoluble protecting layer such as ethyl cellulose exists on the tooth-adhering layer consisting of the hydrophilic polymers. Also, the patches require caution in use due to the following reason. When hydration makes very rapid progress and thus, the patches loses adhesive strength, the whole or a portion of a backing layer may be detached from the patches and stick in one's throat, thereby causing safety risks.

Also, since the conventional film formulation as described above has a level of peroxides stability lower than that of the formulation using gel, the film is prepared under an acid condition.

However, such an acid condition makes it difficult for peroxides to dissolve when the film adhered to the teeth, stimulates the gum and causes a strong aversion. There is a further problem that since the dissolution rate is low, the film should be applied to the teeth for a long time. It has been known that the more time is required for whitening the yellow-stained teeth caused by taking tetracycline(antibiotics) or smoking than that caused by taking food. In a general way, the conventional tooth-whitening agent should be applied for a prescribed time and removed since it has a water-insoluble substance or structure, thereby causing lots of problems in case of a long-time application. Therefore, it is required for developing a tooth-whitening patch which is improved in the above-described several problems and safety risks.

Thus, the present inventors prepared a patch for tooth whitening wherein a hydrophilic polymers and combination thereof having a various dissolution rates are used and during being applied to the teeth, they release peroxides at an appropriate rate and then they are eroded and completely vanished from the teeth surfaces in order to solve several problems in use and techniques of the conventional tooth-whitening patch in the form of strip or film, i.e., inconvenience of removing it from the tooth after use, safety risk in case losing adhesive strength, thereby plugging us one's throat with

the detached water-insoluble protecting layer, difficulty in using before sleeping and aversion to a foreign substance in the teeth or the mouth.

The tooth-whitening patch of the present invention is characterized in that it contains peroxides as a tooth-whitening agent; it is a tooth-whitening agent in the form of film able to adhere to the teeth for a sufficient time; the polymer film is hydrated when applied to the teeth at the same time, releases peroxides; and then the film is eroded and vanished gradually from the teeth surfaces, thereby seriously improving the convenience in use, removing the safety problem, and showing excellent whitening effects in a short time.

【Technical problem to be solved by the invention】

The purpose of the present invention is to provide a new patch for tooth whitening wherein the patch contains peroxides within an erodible polymer film, thereby making the film be hydrated after being applied to the teeth at the same time of releasing the peroxides and then the film is gradually eroded and vanished from the teeth.

【Constitution of the invention】

In order to establish the above-said purpose, the present invention provides a patch for tooth whitening wherein the patch is in the form of film containing a tooth-whitening agent and is hydrated after being applied to the teeth and releases a whitening agent and then it is eroded and vanished.

More particularly, the present invention provides a new tooth-whitening patch and a new method of whitening characterized in that the patch of the present invention uses the erodible polymer film and is hydrated by water in the mouth when it is applied to the teeth and release peroxides, a whitening agent, and is completely eroded from the teeth, so it is convenient in use because we do not have to remove the residue after whitening the tooth and it is possible to use during sleeping and further a safety risk accompanying using water-insoluble material and aversion to a foreign substance are improved.

As for the patch of the present invention, it is possible to use the film under dry condition or wet condition, preferably under dry condition.

The erodible polymer film contains the hydrophilic polymers such as a water-soluble polymer and a water-swollen polymer which are hydrated by water in the mouth when applied to the teeth and release the peroxides and after some time, they erode by themselves and vanish away.

The patch needs 10 minutes to 3 hours, preferably 30 minutes to 1 hour, as an adhesion time after being applied to the teeth. The adhesion time depends on the erosion rate of the polymer film and further the erosion rate depends on a sort of the used polymers and a structure of the layer thereof.

Since the present invention is characterized mainly in that the patch is completely eroded and vanished away in a prescribed time after being applied to the teeth, the polymer used in the present invention is one or more polymer selected from the group with a hydrophilic property regardless of a position of each layer such as an erodible drug layer, an erosion rate-controlling layer, a layer containing a peroxide activator, and the hydrophilic polymer according with the above-said purpose is selected from the group of polyvinylpyrrolidone(PVP), polyvinylalcohol (PVA), polyvinylpyrrolidone-vinylacetate copolymer(PVP/VA copolymer), polyquaterium-11, polyquaterium like polyquaterium-39, polyalkyl vinyl ether-maleic acid copolymer(PVM/MA copolymer, Gantrez), poloxamer, carbopol, carbomer, polyethylene oxide(PEO), polyacrylic acid(PAA), polymetaacrylic acid(PMAA), hydroxyethyl cellulose(HEC), hydroxypropyl methyl cellulose(HPMC), carboxy methyl cellulose(CMC), hydroxypropyl cellulose(HPC), methyl cellulose(MC), sodium carboxy methyl cellulose(NaCMC), acrylic acid copolymer, metacrylic acid copolymer such as eudragit, sodium alginate, gelatin, alginic acid, chitosan. These hydrophilic polymers have been used for a coating, a binder, a disintegrant, a controlled release formulation, a solubilizer and the like so far and safety thereof has already been proved and according to the features of the present invention, the patch for tooth whitening is completely harmless even if it is eroded and

swallowed in the body through a throat.

In case of a tooth-whitening patch is in the form of a single layer, the polymer can be one compound or a mixing one or more polymers. In case of a tooth-whitening patch is in the form of multi layers more than two, as set in forth before, each layer can be selected from the same sort of hydrophilic polymers or from the different sorts of hydrophilic polymers. Even in case of a multi layers, each layer can be comprised of more than two hydrophilic polymers different from each other at a proper ratio, thereby obtaining various erosion rates. Polymer containing more than two sorts can be a form of simply a physical mixing compound and can form a complex through a polymer interaction such as an ionic bond and a hydrogen bond.

Another method for obtaining various erosion rates is to mix a hydrophilic polymer with a water-insoluble polymer, but in case that the mixture is hydrated, a film can be opaque or deposited by the water-insoluble polymer, thereby getting the teeth dirty during the adhesion time, reducing an adhesion power to the teeth or changing the erosion properties, so it is undesirable. Therefore, the tooth-whitening patch of the present invention, wherein the patch is erodible and not necessary to be removed, is characterized in that the patch uses only hydrophilic polymer such as water-soluble and water-swollen polymers or a mixture thereof and in order to show a sufficient tooth-whitening effect, it should be adhered to the teeth for at least 10 minutes to 3 hours, preferably 30 minutes to 1 hour.

A tooth-whitening patch should be adhered to the teeth easily and pliable according to tooth curve, so it should be sufficiently supple. Some polymers are not sufficiently supple, so it may be possible to add a proper plasticizer thereto. The proper plasticizer is specific to a sort of polymer, but propylene glycol, glyceroltriethylcitrate, sorbitol and polyethylene glycol are generally used and available.

It is possible to use a whitening agent in the erodible tooth-whitening patch of the present invention by mixing more than one selected from the group consisting of hydrogen peroxide, carbamide peroxide, calcium peroxide, calcium chlorite, barium chlorite, magnesium

chlorite, lithium chlorite, sodium chlorite, sodium percarbonate, sodium perborate, tetrasodium pyrophosphate peroxidate.

Also, in order to keep a stability in the patch of the present invention while keeping the peroxides, it is possible to add the generally-known peroxide-stabilizing agent, for Example, ethylenediaminetetraacetic acid (EDTA), citric acid. Dequest phosphonate chelate, sorbitan monolaurate (SML), sorbitan monopalmitate (SMP), sorbitan stearate, sorbitan monooleate (SMO), sorbitan oleate, sorbitan trioleate and POE sorbitan fatty acid ester surfactants.

Further, a condensed polyphosphate which is known for contributing to a stability of peroxides is a suitable chelating agent for metal and is able to efficiently remove tooth stain made by metal such as iron, calcium, magnesium and the like originated from food or working place, thereby contributing to whitening effectiveness. The condensed polyphosphate usable for the tooth-whitening patch of the present invention is a mixture of more than one selected from sodium methaphosphate, potassium methaphosphate, sodium hexamethaphosphate, tetrasodium pyrophosphate, sodium acid pyrophosphate and sodium tripolyphosphate.

In order to improve whitening effects, a peroxide activator can be used in the present invention. The peroxide activator can be, for Example, a metal ion such as Fe, Cu, Pd, Mn or its salt, charcoal, each of alkaline sodium carbonate and sodium hydroxides and their compound, and prior to using it, in order to a stability of peroxides in the patch, it is possible to use a probiont of the activator which is contained in a peroxide free layer or hydrated and acts as activator after being applied to the teeth. The probiont of the activator can be, for Example, sodium oxide, magnesium oxide, calcium oxide and the like.

The formulation used in the present invention can further contain a substance able to produce a fluorine ion to prevent a tooth decay or a tin ion to reduce gingivitis or plaque.

The substance able to produce a fluorine ion is sodium fluoride, potassium fluoride, stannous fluoride, monofluoride phosphate(MFP),

ammonium fluoride and the like.

The substance able to produce a tin ion is stannous fluoride, stannous acetate, stannous gluconate, stannous oxalate, stannous malonate, stannous citrate, stannous ethylene glycoside, stannous formate and the like.

Also, the tooth-whitening formulation can further contains xylitol. The xylitol is a pentoses alcohol and used as a sweetening agent or a moistening agent and excellent in fighting bacteria and preventing a tooth decay.

Besides, various colors of pigment or perfume, sweetening agent, moistening agent and the like can be added. The perfume can be peppermint, spearmint, winter green, sage, eucalyptus oil, methyl salicylate and the other fruit extracts and the sweetening agent can be lactose, aspartame, saccharin sodium and the like.

Also, the present invention provides a patch for whitening in characterized for comprising a single layer containing an erodible drug layer or more than one erosion rate-controlling layer adhered thereto or multi layers containing a peroxide activator.

More particularly, the patch of the present invention consists of at least one layer, and in case of a structure consisting of a single layer, the erodible drug layer consists of peroxides, a peroxide-stabilizing agent and the other all pharmaceutical excipients as well as hydrophilic polymers in the form of a film matrix.

In case of a structure consisting of more than two layers, it is possible to manufacture it by accumulating more than one hydrated or erodible layer which is identical with an erodible drug layer or different from it on or under the drug layer containing peroxides.

In order to do so, the hydrophilic polymers used in the erodible drug layer can be different from that used in another erosion rate-controlling layer and it is possible to form each layer only using various polymers or properly mixing them considering the features of adhesion to the tooth, hydration and erosion. Also, the peroxide activator, peroxide-stabilizing agent and the like can be further added to each layer regardless a sort of hydrophilic polymer and a feature of

erosion.

In a desirable Example of the present invention, a whitening patch in the structure of a single layer only consisting of dry erodible drug layer is provided and in another Example, a whitening patch in the structure of a dry double-layer consisting of an erodible drug layer containing peroxides and adhered to the tooth as a lower layer and an erosion rate-controlling layer as a upper layer.

In the above-said whitening patch of the present invention, peroxides can be contained in either lower or upper layer or in both layers, desirably in the lower layer adhered to the tooth.

The present invention provides a dry triple-layer structure in another Example and the lower layer is an erodible drug layer containing peroxides and adhered to the tooth, and the middle layer and the upper layer have erosion rate layers functioning differently from each other.

Peroxides can be contained in whichever layer, desirably in the lower layer adhered to the tooth. Each layer can have a different hydration or erosion rate and in order to do so, it is possible to manufacture with hydrophilic polymers different from one another and the compounds thereof. If necessary for function and manufacturing process, the number of layers can be over 4 and in the present invention does not limit the number of the layer.

There are two methods for manufacturing an erodible tooth-whitening patch in the structure of multi layers described in the present invention. First method is a multiple coating method, wherein a first layer is applied and then second and third layers are applied on the first one repeatedly or the other method is a coating-lamination method, wherein respective layers are applied and manufactured and then adhered to one another.

For Example, the multiple coating method for manufacturing a tooth-whitening patch in the structure of double layers is as follows. First thing to do is dissolving hydrophilic polymers, peroxides and the like forming an erodible drug layer in a proper solvent, which is the solvent selected from water, ethanol, methanol, isopropanol, acetone, ethylacetate and methylenchloride or the solvent mixed with them in the

ratio of about 1:0.1 to 1:10, desirably the solvent mixed with water and ethanol in the ratio 6:4 and then to do is stirring them, thereby obtaining a homogeneous coating solution and then applying it to a release paper with a spreading machine and completing the erodible drug layer by drying it at the temperature of 40°C to 80 °C, desirably at 60 °C and then applying a mixed solution for controlling the erosion rate on the erodible drug layer and drying it again at the temperature of 40°C to 80°C, thereby obtaining the erodible tooth-whitening patch in the structure of double layers.

The erodible tooth-whitening patch consisting of more than three layers can be manufactured by applying and drying the upper layers of double layers repeatedly.

The erodible tooth-whitening patch of the present invention can be transformed to various forms according to each person's tooth form. For Example, it is possible to make a transformation as shown in Figs. 1 to 6, but the present invention does not only limit the formations as shown in the above-said figures.

The present invention is explained in detail as below by the Examples and the Experimental Examples.

However, the following Examples and Experimental Examples just illustrate the present invention, but it is not limited by the following Examples and the Experimental Examples.

Example 1. Preparing an erodible tooth-whitening patch containing peroxides in the structure of a single layer

In order to provide a film patch for whitening tooth, a coating solution is prepared by using the substances listed in the below Table 1. That is, carbopol(Carbopol) 934P, hydroxypropyl cellulose(HPC), polyethylene glycol(PEG), hydrogen peroxide, sodium acid pyrophosphate(SAPP), sorbitan monolaurate(SML) and peppermint composed according to the ratio indicated in the below Table 1 are put into the solution mixed with water and ethanol in the ratio of 6:4, stirred with a stirrer (IKA Mixer), thereby preparing a homogeneous coating solution. The homogeneous coating solution is applied on a release

paper(PET film, SK) with a spreading machine(Mathis Dry Coater) and the release paper is dried at the temperature of 60℃, thereby completing a film patch for whitening the tooth.

【Table 1】

| | |
|-----------|---|
| Example 1 | Preparation from Carbopol 2%, HPC 8%, PEG 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
|-----------|---|

Example 2-29. Preparation Example of a tooth-whitening patch in the structure of a single layer

An erodible tooth-whitening patch containing peroxides in the structure of a single layer is prepared by mixing the substances indicated in the below Table 2 according to the method described in Example 1.

【Table 2】

| | Components ratio |
|------------|--|
| Example 2 | Preparation from HPC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 3 | Preparation from PVP/VA 20%, glycerine 5%, hydrogen peroxide 2%, SMO 3%, mint 2%, ethanol |
| Example 4 | Preparation from gantrez 20%, PG 5%, hydrogen peroxide 2%, SMO 3%, mint 2%, ethanol |
| Example 5 | Preparation from polyquaterium-11 20%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 6 | Preparation from carbopol 3%, glycerine 5%, carbamide peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 7 | Preparation from PVA 15%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, purified water |
| Example 8 | Preparation from HPMC 10%, PEG 3%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(5:5) |
| Example 9 | Preparation from HEC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, purified water |
| Example 10 | Preparation from PAA 15%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 11 | Preparation from PEO 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, purified water |
| Example 12 | Preparation from gelatin 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, purified water |
| Example 13 | Preparation from sodium alginate 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, purified water |

| | |
|---|--|
| Example 14 | Preparation from PVA 10%, PVP 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(2:8) |
| Example 15 | Preparation from carbopol 5%, poloxamer 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Components ratio |
| Example 16 | Preparation from PVA 7%, PEO 7%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, purified water |
| Example 17 | Preparation from PAA 5%, HEC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 18 | Preparation from carbopol 3%, PVP/VA 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 19 | Preparation from gantrez 7%, PVP/VA 8%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 20 | Preparation from eudragit 1%, HPMC 9%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 21 | Preparation from sodium alginate 5%, PVP/VA 5%, HPMC 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 22 | Preparation from PVP 5%, PEO 5%, PAA 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 23 | Preparation from gantrez 5%, HPC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 24 | Preparation from gantrez 10%, NaCMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 25 | Preparation from PAA 5%, PEO 5%, HEC 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 26 | Preparation from HPMC 10%, HPC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 27 | Preparation from HEC 10%, HPMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 28 | Preparation from carbopol 3%, NaCMC 7%, PEG 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 29 | Preparation from carbopol 3%, HPMC 10%, PEG 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| SAPP: sodium acid pyrophosphate, TSPP: (tetrasodium pyrophosphate, HPC: hydroxypropyl cellulose, PVP: polyvinyl pyrrolidone, SML: sorbitan monolaurate, PVP/VA: polyvinyl pyrrolidone/vinylacetate, SMO: sorbitan monooleate, PG: propylene glycol, PVA: polyvinyl alcohol, HPMC: hydroxypropyl methyl cellulose, PEG: polyethylene glycol, SnF: stannous fluoride, HEC: hydroxy ethyl cellulose, EDTA: ethylene diamine tetraacetic acid, PAA: polyacrylic acid, PEO: polyethylene oxide, NaCMC: sodium carboxy methyl cellulose and MC: methyl cellulose. | |

Example 30. Preparing an erodible tooth-whitening patch containing peroxides in the structure of double layers

In order to provide a film formulation for whitening the tooth, a coating solution is prepared using the substances listed in Table 3. A solution for a upper layer and another solution for a lower solution are prepared according to the components ratio listed in Table 3. The solution for a lower layer is applied on a release paper(PET film, SK) with a spreading machine(Mathis Dry Coater) and the release paper is dried at the temperature of 60℃ and the solution for the upper layer is applied thereon and the film patch for whitening the tooth is completed.

【Table 3】

| | |
|-------------|---|
| Lower layer | Preparation from HPC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Upper layer | Preparation from HPMC 10%, PEG 400 3%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |

Example 31-60. Preparation of an erodible tooth-whitening patch containing peroxides in the structure of double layers

An erodible tooth-whitening patch containing peroxides in the structure of double layers is prepared by mixing the substances listed in the below Table 4 according to the method of Example 30.

【Table 4】

| | | Components ratio |
|------------|-------------|---|
| Example 31 | Lower layer | Preparation from PVA 15%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, purified water |
| | Upper layer | Preparation from HPC 10%, mint 2%, ethanol/purified water(4:6) |
| Example 32 | Lower layer | Preparation from carbopol 3%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPMC 10%, MgO 2%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 33 | Lower layer | Preparation from HPC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HEC 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 34 | Lower layer | Preparation from gelatin 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |

| | | |
|------------|-------------|---|
| | Upper layer | Preparation from PVA 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 35 | Lower layer | Preparation from eudragit 20%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from PEO10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 36 | Lower layer | Preparation from gantrez 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPC 10%, eudragit 5%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 37 | Lower layer | Preparation from carbopol 3%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from PVA 10%, boric acid 0.5%, glycerine 10%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 38 | Lower layer | Preparation from PVP/VA 20%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from sodium alginate(Sodium Alginate) 10%, MC 5%, HPC 5%, glycerine 5%, MgO 3%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 39 | Lower layer | Preparation from HPC 20%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from PVA 10%, PEO 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 40 | Lower layer | Preparation from Polyquaterium-11 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPC 10%, HPMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 41 | Lower layer | Preparation from PEO 20%, glycerine 5%, hydrogen peroxides 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from PAA 15%, glycerine 5%, hydrogen peroxides 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 42 | Lower layer | Preparation from PAA 15%, glycerine 5%, hydrogen peroxides 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from gantrez 10%, PVP/VA 10%, glycerine 5%, hydrogen peroxides 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 43 | Lower layer | Preparation from carbopol 5%, NaCMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |

| | | |
|------------|-------------|--|
| | Upper layer | Preparation from HPC 10%, glycerine 5%, hydrogen peroxides 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6)로 100% |
| Example 44 | Lower layer | Preparation from carbopol 5%, poloxamer 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from MC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 45 | Lower layer | Preparation from carbopol 3%, poloxamer 10%, HEC 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 46 | Lower layer | Preparation from PEO 5%, HPC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from PVA 15%, HPC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 47 | Lower layer | Preparation from PEO 10%, HPMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from eudragit 10%, PVP 3%, HPMC 5%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 48 | Lower layer | Preparation from PVP 10%, PVA 3%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPC 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 49 | Lower layer | Preparation from eudragit 10%, HPC 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from carbopol 5%, poloxamer 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 50 | Lower layer | Preparation from sodium alginate 5%, HPC 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPC 10%, HPMC 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 51 | Lower layer | Preparation from gantrez 10%, HPC 10%, PVP/VA 5%, glycerine 5%, hydrogen peroxides 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPMC 10%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |

| | | |
|------------|-------------|---|
| Example 52 | Lower layer | Preparation from carbopol 3%, HPMC 5%, HPC 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from eudragit 10%, HPC 5%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 53 | Lower layer | Preparation from PVA 5%, HPMC 5%, HPC 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from NaCMC 5%, gantrez 5%, PVP/VA 5%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 54 | Lower layer | Preparation from carbopol 3%, HPMC 5%, HPC 5%, glycerine, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from carbopol 3%, HPMC 5%, HPC 5%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 55 | Lower layer | Preparation from carbopol 3%, HPMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from PEO 10%, gantrez 5%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 56 | Lower layer | Preparation from carbopol 3%, HPMC 10%, PEG 10%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPC 20%, PEG 10%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 57 | Lower layer | Preparation from carbopol 3%, HPMC 10%, glycerine 5%, hydrogen peroxide 1%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPC 20%, hydrogen peroxide 1%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 58 | Lower layer | Preparation from HPC 10%, HPMC 10%, xylitol 2%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from HPC 10%, HPMC 10%, xylitol 2%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 59 | Lower layer | Preparation from HPC 10%, HPMC 10%, xylitol 2%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Upper layer | Preparation from MC 10%, HPMC 10%, glycerine 5%, MgO 3%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| Example 60 | Lower layer | Preparation from HPC 10%, HPMC 10%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |

| | | |
|--|-------------|--|
| | Upper layer | Preparation from MC 10%, HPMC 10%, CaO 3%, glycerine 5%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
|--|-------------|--|

Example 61. Preparation of an erodible tooth-whitening patch containing peroxides in the structure of triple layers

In order to provide a film formulation for whitening the tooth, a coating solution is prepared using the substances listed in Table 5. A solution for a upper layer, a solution for a middle layer and a solution for a lower solution are prepared according to the components ratio listed in Table 5. The solution for a lower layer is applied on a release paper(PET film, SK) with a spreading machine(Mathis Dry Coater) and the release paper is dried at the temperature of 60°C and the solutions for the middle and upper layers are applied thereon and the film patch for whitening the tooth is completed.

【Table 5】

| | |
|--------------|--|
| Lower layer | Preparation from HFC 10%, hydrogen peroxide 3%, SAPP 2%, SML 3%, ethanol/purified water(4:6) |
| Middle layer | Preparation from HPMC 10%, PEG 3%, ethanol/purified water(5:5) |
| Upper layer | Preparation from HPMC 5%, MC 5%, PEG 2%, MgO 2%, mint 2%, ethanol/purified water(5:5) |

Example 62-79. Preparation of an erodible tooth-whitening patch in the structure of triple layers

An erodible tooth-whitening patch containing peroxides in the structure of triple layers is prepared by mixing the substances listed in the below Table 6 according to the method of Example 61.

【Table 6】

| | | Components ratio |
|------------|--------------|---|
| Example 62 | Lower layer | Preparation from HPC 8%, carbopol 2%, glycerine 5%, hydrogen peroxide 2%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(4:6) |
| | Middle layer | Preparation from HPMC 6%, MC 4%, SAPP 2%, SML 3%, mint 2%, ethanol/purified water(5:5) |
| | Upper layer | Preparation from HPMC 4%, MC 6%, SML 3%, CaO 2%, mint |

| | | |
|------------|--------------|---|
| | | 2%, ethanol/purified water(5:5) |
| Example 63 | Lower layer | Preparation from HPC 5%, carbopol 5%, poloxamer 5%, hydrogen peroxide 2%, SAPP 2%, SML 3% |
| | Middle layer | Preparation from HPMC 10%, PEG 3%, ethanol/purified water(5:5) |
| | Upper layer | Preparation from MC 5%, PEG 2%, mint 2%, ethanol/purified water(5:5) |
| Example 64 | Lower layer | Preparation from carbopol 5%, HPMC 5%, PEG 3%, hydrogen peroxide 2%, SAPP 3%, SML 2%, ethanol/purified water(4:6) |
| | Middle layer | Preparation from HPMC 4%, MC 6%, SML 3%, CaO 2%, mint 2%, ethanol/purified water(5:5) |
| | Upper layer | Preparation from MC 5%, PEG 2%, mint 2%, ethanol/purified water(5:5) |
| Example 65 | Lower layer | Preparation from gantrez 10%, hydrogen peroxide 4%, PG 3%, TSPP 2%, SMO 3%, ethanol |
| | Middle layer | Preparation from PEO 10%, glycerine 3%, MgO 2%, purified water |
| | Upper layer | Preparation from HPMC 5%, MC 5%, PEG 3%, ethanol/purified water(5:5) |
| Example 66 | Lower layer | Preparation from PVP 10%, hydrogen peroxide 3%, glycerine, SAPP 2%, SML 3%, ethanol/purified water(4:6) |
| | Middle layer | Preparation from HPMC 5%, PEG 2%, NaO 2%, ethanol/purified water(5:5) |
| | Upper layer | Preparation from eudragit 15%, PG 5%, SMO 3%, ethanol |
| Example 67 | Lower layer | Preparation from PAA 10%, hydrogen peroxide 3%, glycerine 2%, SAPP 2%, SML 3%, ethanol/purified water(4:6) |
| | Middle layer | Preparation from HEC 5%, PVP 5%, glycerine 2%, purified water |
| | Upper layer | Preparation from MC 10%, PEG 2%, ethanol/purified water(5:5) |
| Example 68 | Lower layer | Preparation from HPC 15%, hydrogen peroxide 3%, SAPP 2%, SML 3%, ethanol/purified water(4:6) |
| | Middle layer | Preparation from PVP 10 %, glycerine 3 %, ethanol/purified water (4:6) |
| | Upper layer | Preparation from HPMC 5 %, PEG 2 %, ethanol/purified water (4:6) to 100 % |
| Example 69 | Lower layer | Preparation from gantrez 10 %, PG 3 %, MgO 2 %, ethanol |
| | Middle layer | Preparation from PVP 15 %, glycerine 3 %, hydrogen peroxide 3 %, SAPP 2 %, SML 3 %, ethanol/purified water(4:6) layer |
| | Upper layer | Preparation from PEO 10 %, PVP 5 %, glycerine 5 %, ethanol/purified water (4:6) |
| Example 70 | Lower layer | Preparation from PVP/VA 15 %, hydrogen peroxide 2 %, glycerine 3 %, TSPP 2 %, ethanol |

| | | |
|------------|--------------|--|
| | Middle layer | Preparation from HEC 15 %, PEG 2 %, NaOH 2 %, mint 2 %, purified water |
| | Upper layer | Preparation from eudragit 15 %, PG 5 %, SML 3 %, ethanol |
| Example 71 | Lower layer | Preparation from polyquaterium-11 10 %, hydrogen peroxide 3 %, PG 3 %, ethanol |
| | Middle layer | Preparation from NaCMC 2 %, carbopol 2 %, PEG 1 %, MgO 2 %, purified water |
| | Upper layer | Preparation from MC 10 %, PEG 2 %, ethanol/purified water(5:5) |
| Example 72 | Lower layer | Preparation from PVP/VA 15 %, hydrogen peroxide 3 %, glycerine 3 %, TSPP 2 %, ethanol |
| | Middle layer | Preparation from sodium alginate 10 %, glycerine 3 %, purified water |
| | Upper layer | Preparation from HPMC 5 %, MC 5 %, PEG 2 %, mint 2 %, ethanol/purified water(5:5) |
| Example 73 | Lower layer | Preparation from HPC 15 %, carbamide peroxide 9 %, SMO 3 %, SAPP 2 %, ethanol |
| | Middle layer | Preparation from HEC 10 %, PEG 2 %, sodium bicarbonate 3 %, purified water |
| | Upper layer | Preparation from eudragit 15 %, PG 5 %, SML 3 %, ethanol |
| Example 74 | Lower layer | Preparation from PVP 10 %, carbamide peroxide 9 %, glycerine 3 %, SAPP 2 %, SML 3 %, ethanol/purified water(4:6) |
| | Middle layer | Preparation from PEO 5 %, PAA 5 %, PEG 2 %, purified water |
| | Upper layer | Preparation from PVA 10 %, HEC 5 %, glycerine 3 %, mint 3 %, purified water |
| Example 75 | Lower layer | Preparation from gantrez 10 %, hydrogen peroxide 3 %, PG 3 %, SMO 3 %, ethanol |
| | Middle layer | Preparation from Polyquaterium-39, PG 3 %, ethanol |
| | Upper layer | Preparation from HEC 5 %, HPMC 5 %, PEG 2 %, FeSO4 1 %, mint 2 %, ethanol/purified water(5:5) |
| Example 76 | Lower layer | Preparation from carbopol 5 %, poloxamer 10 %, carbamide peroxide 9 %, SAPP 2 %, SML 3 %, ethanol/purified water(4:6) |
| | Middle layer | Preparation from PVP/VA 10 %, HPC 5 %, MnSO4 1 %, ethanol |
| | Upper layer | Preparation from HPMC 10 %, PEG 2 %, mint 2 %, ethanol/purified water(5:5) |
| Example 77 | Lower layer | Preparation from PEO 10 %, glycerine 5 %, hydrogen peroxide 2 %, SAPP 2 %, SML 3 %, mint 2 %, purified water |
| | Middle layer | Preparation from HPMC 10 %, PEG 2 %, sodium bicarbonate 2 %, ethanol/purified water(5:5) |
| | Upper layer | Preparation from eudragit 2 %, PVP 8 %, mint 2 %, ethanol/purified water(4:6) |
| Example 78 | Lower layer | Preparation from carbopol 3 %, NaCMC 3 %, PEG 2 %, carbamide peroxide 10 %, SAPP 2 %, SML 3 %, mint 2 %, ethanol/purified water(4:6) |

| | | |
|------------|--------------|--|
| Example 79 | Middle layer | Preparation from sodium alginate 10%, glycerine 3%, purified water |
| | Upper layer | Preparation from PVA 10%, PEO 5%, glycerine 3%, purified water |
| | Lower layer | Preparation from HEC 5%, PVP 5%, HPC 5%, glycerine 3%, hydrogen peroxide 3%, SAPP 3%, purified water |
| | Middle layer | Preparation from gantrez 10%, PG 3%, NaOH 2%, ethanol |
| | Upper layer | Preparation from MC 5%, HEC 5%, PEG 2%, purified water |

Experimental Example 1. Comparison of adhesion time of an erodible high polymer patch for whitening the tooth

Experimental fraction for the upper tooth was applied to a subject person. An adhesion time was obtained by measuring the time from when the erodible high polymer film patch for whitening is applied to the tooth to when the patch is eroded and vanished away completely from the tooth.

【Table 7】

| | Adhesion time(min) | | Adhesion time(min) |
|------------|--------------------|------------|--------------------|
| Example 1 | 30 | Example 32 | 55 |
| Example 2 | 25 | Example 35 | 60 |
| Example 4 | 20 | Example 38 | 20 |
| Example 5 | 25 | Example 41 | 25 |
| Example 8 | 35 | Example 45 | 65 |
| Example 10 | 20 | Example 47 | 60 |
| Example 11 | 15 | Example 55 | 30 |
| Example 14 | 25 | Example 58 | 55 |
| Example 15 | 40 | Example 61 | 75 |
| Example 16 | 35 | Example 62 | 80 |
| Example 17 | 20 | Example 63 | 75 |
| Example 19 | 20 | Example 64 | 70 |
| Example 22 | 25 | Example 68 | 35 |

| | | | |
|------------|----|------------|----|
| Example 24 | 25 | Example 71 | 45 |
| Example 26 | 30 | Example 72 | 40 |
| Example 29 | 40 | Example 74 | 45 |
| Example 30 | 50 | Example 76 | 60 |
| Example 31 | 25 | Example 79 | 55 |

As shown in Table 7, various adhesion times could be obtained according to a sort of high polymers and a feature of dissolution thereof.

【Effect of the invention】

As reviewed above, the tooth-whitening patch in the form of the erodible high polymer film of the present invention contains peroxide compounds as a tooth-whitening agent in the patch and the film used in the patch is hydrated and releases tooth-whitening agent after being applied to the teeth and then it is eroded and vanished, thereby greatly reducing aversion to a foreign substance. Also, it is different from an inconvenient patch which should be applied for a prescribed time and removed from the teeth in that it is eroded by water in the mouth by itself and vanished, thereby making it convenient in use and providing an excellent whitening effect in a short time.

【What is claimed is】

【Claim 1】

A patch for tooth whitening to be adhered to tooth, wherein the patch is in the form of film consisting a tooth-whitening agent and after adhered to tooth and hydrated, it releases a whitening agent, thereby being eroded and vanished.

【Claim 2】

The patch as set forth in Claim 1, wherein the film is dry or wet.

【Claim 3】

The patch as set forth in Claim 1, wherein the patch can be adhered to tooth between 10 minutes and three hours after being adhered to tooth.

【Claim 4】

The patch as set forth in Claim 3, wherein the patch can be adhered to tooth between thirty minutes and one hour.

【Claim 5】

The patch as set forth in Claim 1, wherein an erodible polymer film is used.

【Claim 6】

The patch as set forth in Claim 5, wherein the patch for tooth whitening consisting of only polymers with hydrophile property such as water-soluble or water-swollen high polymers, thereby being eroded and vanished completely in the mouth.

【Claim 7】

The patch as set forth in Claim 6, wherein one or more polymers with hydrophile property available to be used for the patch for tooth whitening is selected from the group of polyvinylpyrrolidone(PVP),

polyvinylalcohol (PVA), polyvinylpyrrolidone-vinylacetate copolymer(PVP/VA copolymer), polyquaterium-11, polyquaterium like polyquaterium-39, polyalkyl vinyl ether-maleic acid copolymer(PVM/MA copolymer, Gantrez), poloxamer, carbopol, carbomer, polyethylene oxide(PEO), polyacrylic acid(PAA), polymetaacrylic acid(PMAA), hydroxyethyl cellulose(HEC), hydroxypropyl methyl cellulose(HPMC), carboxy methyl cellulose(CMC), hydroxypropyl cellulose(HPC), methyl cellulose(MC), sodium carboxy methyl cellulose(NaCMC), acrylic acid copolymer, metacrylic acid copolymer, sodium alginate, gelatin, alginic acid, chitosan.

[Claim 8]

The patch as set forth in Claim 1, wherein one or more polymers with hydrophile property available to be comprised in the patch for tooth whitening is selected from the group of hydrogen peroxide, carbamide peroxide, calcium peroxide, calcium chlorite, barium chlorite, magnesium chlorite, lithium chlorite, sodium chlorite, sodium percarbonate, sodium perborate, tetrasodium pyrophosphate peroxidate.

[Claim 9]

The patch as set forth in Claim 1, further comprising a plasticizer.

[Claim 10]

The patch as set forth in Claim 9, wherein one or more plasticizer is selected from the group consisting of propylene glycol, glycerol, triethylcitrate, sorbitol, polyethylene glycol and glycerine.

[Claim 11]

The patch as set forth in Claim 1, further comprising a peroxide-stabilizing agent.

[Claim 12]

The patch as set forth in Claim 1, wherein one or more

peroxide-stabilizing agent is selected from the group consisting of ethylenediaminetetraacetic acid (EDTA), citric acid, Dequest phosphonate chelate, sorbitan monolaurate (SML), sorbitan monopalmitate (SMP), sorbitan stearate, sorbitan monooleate (SMO), sorbitan oleate, sorbitan trioleate and POE sorbitan fatty acid ester surfactants and then mixed for use.

[Claim 13]

The patch as set forth in Claim 1, further comprising a condensed polyphosphate.

[Claim 14]

The patch as set forth in Claim 13, one or more condensed polyphosphate is selected from the group consisting of sodium methaphosphate, potassium methaphosphate, sodium hexamethaphosphate, tetrasodium pyrophosphate, sodium acid pyrophosphate and sodium polyphosphate.

[Claim 15]

The patch as set forth in Claim 1, further comprising a peroxide activator or a probiant of the activator.

[Claim 16]

The patch as set forth in Claim 15, wherein one or more peroxide activator is selected from the group consisting of metallic ions such as Fe, Cu, Pd and Mn or their salts, charcoal, alkalie sodium carbonate and sodium hydroxide.

[Claim 17]

The patch as set forth in Claim 15, wherein one or more probiant of the peroxide activator is selected from the group consisting of oxidized sodium, oxidized magnesium and oxidized calcium.

[Claim 18]

The patch as set forth in Claim 1, comprising fluorine-containing compounds to prevent tooth decay or tin-containing compounds and the like to reduce gingivitis or plaque.

[Claim 19]

The patch as set forth in Claim 18, wherein one or more fluorine-containing compounds are selected from the group consisting of sodium fluoride, potassium fluoride, stannous fluoride, monofluoride phosphate (MFP) and ammonium fluoride.

[Claim 20]

The patch as set forth in Claim 18, wherein one or more tin-containing compounds are selected from the group consisting of stannous fluoride, stannous acetate, stannous gluconate, stannous oxalate, stannous malonate, stannous citrate, stannous ethylene glycoside and stannous formate.

[Claim 21]

The patch as set forth in Claim 1, further comprising one or more compounds which are selected from the group consisting of xylitol, pigment, sweetening agent and moistening agent.

[Claim 22]

The patch as set forth in Claim 1, wherein the patch is the form of a multi-layered structure consisting of a single layer or a tooth-adhering layer and more than one erosion rate-controlling layers.

[Claim 23]

The patch as set forth in Claim 22, comprising the single layer which includes an erodible drug layer.

[Claim 24]

The patch as set forth in Claim 22, comprising the multilayer which includes an erodible drug layer and more than one erosion

rate-controlling layers.

【Figures】

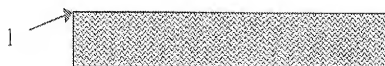
【Fig. 1】



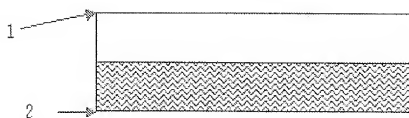
【Fig. 2】



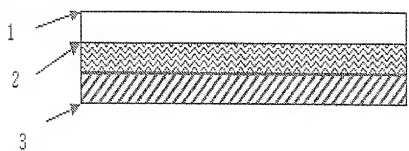
【Fig. 3】



【Fig. 4】



【Fig. 5】



【Fig. 6】

